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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,816	01/22/2004	William J. Shaw	10527-455001	6207

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EXAMINER

STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3774

NOTIFICATION DATE	DELIVERY MODE
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10/21/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/762,816	Applicant(s) SHAW, WILLIAM J.	
	Examiner Alvin J. Stewart	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-25, 33, 36-40 and 52-57 is/are pending in the application.
- 4a) Of the above claim(s) 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-25, 33, 36-40 and 52-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 06/22/09 have been fully considered but they are not persuasive.

Regarding claim 19, the Examiner agrees with the Applicant's representative that **one** embodiment disclose a network of biodegradable polymeric fibers. However, the Application clearly disclose that the above mentioned embodiment is just one preferred embodiment and a plurality of other embodiment can be used with the different materials and combinations. Col. 5, lines 15-26, clearly disclosed that the tubular body can be made with fibers made of metal, ceramics or combinations of the above. The reference clearly disclosed that a combination of different materials can be applied. E.g. metal with ceramics. The only thing missing in the reference is the lack of a metal made of stainless steel or Nitinol. For the above, stainless steel and Nitinol are well know metal materials used in the biomedical art in order to have biocompatible characteristics.

The Examiner is not addressing claims 33 (new limitations) and 52 because they were not examined in the previous office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Litner US Patent 6,589,286 B1.

Litner discloses a tubular structure (10) comprising at least two fibers, the first fiber being a ceramic fiber and a second fiber made of metal, wherein the ceramic fiber is intertwined with the non-ceramic fiber and the device is in the form of a stent (see col. 5, lines 18-26). However, Litner does not disclose a metal made of stainless steel or Nitinol.

NOTE: the prior art specification clearly disclose that the fibers can be combined with different materials, such as, ceramic materials and metal materials, see col. 5, lines 19-21.

Regarding the phrase “greater than one micron” see col. 5, lines 22-24 disclosing a diameter larger than 1 micron.

Regarding claims 23-25, see col. 5, lines 24-25 and 36-40.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the metal of the Litner reference with a metal made of stainless steel and/or Nitinol because Applicant has not disclosed that by having a stainless steel or Nitinol provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the biocompatible metal of the Litner reference because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify the Litner reference to obtain the invention as specified in claim 1.

Claims 33, 36, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radisch, Jr. et al US Patent Pub. 2005/0149102 A1 in view of Dunn et al US Patent 4,655,777.

Radisch, Jr. et al discloses a medical device having a tubular structure (26) and a polymer element (see claim 1) on the tubular structure (see Figs. 2 and 5), wherein the polymer element comprises a ceramic fiber (see claim 9) comprising a metalloid (see boron in claim 9) and the fiber is greater than one micron.

NOTE: claim 9 discloses that the fibers of ceramic can be mixed with a metalloid (boron).

Regarding claims 39 and 40, see paragraph 40.

However, Radisch, Jr. et al does not disclose a ceramic fiber form from about 10 microns to 1,000 microns long.

Dunn et al discloses a method of creating a prosthesis having a polymeric material reinforced by a plurality of ceramic fibers wherein the filaments of the fibers have a ratio of length to the cross sectional area ranging from 10:1 to 1,000,000:1. Dunn et al discloses in col. 7, lines 10-20 an average fiber diameter of 0.074 mm. Therefore, the length of the Dunn et al reference clearly fall within the range discloses by the Applicant between 10 to 1,000 microns because Dunn et al discloses in col. 3, lines 9-12, a ratio of length of the fibers to the cross sectional area between a ratio 10:1 to 1,000,000:1.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Radisch, Jr. et al reference with the diameter and length of the Dunn et al reference in order to maintain a strong patency of the structure and also promote the growth of tissue.

Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radisch, Jr. et al US Patent Pub. 2005/0149102 A1 in view of Dunn et al US Patent 4,655,777 and in further view of Graves, Jr. et al US patent 4,604,097.

Radisch, Jr. et al in view of Dunn et al disclose the invention substantially as claimed. However, Radisch, Jr. et al in view of Dunn et al does not disclose a ceramic fiber from about 1 to 50 microns for the purpose of reinforcing an implant.

Graves, Jr. et al teaches an implant having a polymer with reinforced ceramic fibers having a diameter between 1 to 100 microns (see col. 3, lines 13-21; col. 4, lines 1-7; and table II in col. 6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Radisch, Jr. et al reference in view of Dunn et al with the diameter between 1 to 100 microns of the Graves, Jr. et al reference in order to reinforced a particular area of the implant.

Claims 52, 53 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radisch, Jr. et al US Patent Pub. 2005/0149102 A1 in view of Graves, Jr. et al US Patent 4,604,097.

Radisch, Jr. et al discloses a medical device having a tubular structure (26) and a polymer element (see claim 1) on the tubular structure (see Figs. 2 and 5), wherein the polymer element comprises a ceramic fiber (see claim 9) comprising a metalloid (see boron in claim 9) and the fiber is greater than one micron. However, Radisch, Jr. et al does not disclose a ceramic fiber form from about 1 micron to 50 microns wide.

Graves, Jr. et al teaches an implant having a polymer with reinforced ceramic fibers having a diameter between 1 to 100 microns (see col. 3, lines 13-21; col. 4, lines 1-7; and table II in col. 6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Radisch, Jr. et al reference with the 1 micron to 100 microns wide fibers of the Graves, Jr. et al reference in order to reinforce an implant.

Claims 54, 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radisch, Jr. et al US Patent Pub. 2005/0149102 A1 in view of Graves, Jr. et al US patent 4,604,097 and in further view of Dunn et al US Patent 4,655,777.

Radisch, Jr. et al in view of Graves, Jr. et al disclose the invention substantially as claimed. However, the references do not disclose a ceramic fiber about 10 microns to 100 microns long.

Dunn et al discloses a method of creating a prosthesis having a polymeric material reinforced by a plurality of ceramic fibers wherein the filaments of the fibers have a ratio of length to the cross sectional area ranging from 10:1 to 1,000,000:1. Dunn et al discloses in col. 7, lines 10-20 an average fiber diameter of 0.074 mm. Therefore, the length of the Dunn et al reference clearly fall within the range discloses by the Applicant between 10 to 1,000 microns because Dunn et al discloses in col. 3, lines 9-12, a ratio of length of the fibers to the cross sectional area between a ratio 10:1 to 1,000,000:1.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Radisch, Jr. et al reference with the diameter and length of the Dunn et al reference in order to maintain a strong patency of the structure and also promote the growth of tissue.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella can be reached at 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10/19/09

/Alvin J Stewart/

Primary Examiner, Art Unit 3774